

Serial No. 10/743,373

Dkt.: P-11209.04

Filing Date: December 22, 2003

Title: DISPOSABLE, INTEGRATED EXTRACORPOREAL BLOOD CIRCUIT

Please enter the following amendments to the claims:

1. (Original) A disposable, integrated extracorporeal blood circuit for providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room and employing a venous return line and an arterial line coupled to the respective venous and arterial systems of the patient, the circuit comprising:

a disposable blood pump having a blood pump inlet and a blood pump outlet and adapted to be operated to draw venous blood into the blood pump inlet and pump the venous blood out of the blood pump outlet;

a disposable venous air removal device (VARD) having an upper venous blood inlet coupled to the venous return line and a lower venous blood outlet coupled to the blood pump inlet, whereby venous blood is drawn through the VARD by operation of the blood pump;

a disposable blood oxygenator having an oxygenator venous blood inlet coupled to the blood pump outlet and an oxygenated blood outlet, the blood oxygenator adapted to be operated to oxygenate venous blood pumped by the blood pump into the oxygenator venous blood inlet and discharge oxygenated blood from the oxygenated blood outlet;

a disposable arterial filter having an arterial filter inlet coupled to the oxygenated blood outlet of the blood oxygenator and a arterial filter outlet coupled to the arterial line; and

a disposable circuit support module supporting and spatially arranging the blood oxygenator, the VARD, the arterial filter, and the blood pump in 3-D space with the oxygenator venous blood inlet and the venous blood outlet of the blood pump supported at substantially the same elevation, the lower venous blood outlet of the VARD at a VARD outlet elevation above the venous blood inlet of the blood pump, the arterial line

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coupled to the arterial filter outlet of the arterial filter at an arterial line elevation higher than the VARD outlet elevation, the arterial filter inlet of the arterial filter at an arterial filter inlet elevation higher than the arterial line elevation, and the venous return line coupled to the upper venous blood inlet of the VARD at a venous return line elevation, whereby the operation of the blood pump is assisted by gravity flow of venous blood through the venous return line and the VARD.

2. (Original) The extracorporeal blood circuit of Claim 1, wherein the VARD further comprises:

- a VARD housing enclosing a lower VARD chamber coupled to the lower venous blood outlet and an upper VARD chamber coupled to the upper venous blood inlet;
- a VARD purge port through the housing to the upper VARD chamber; and
- an air sensor supported by the VARD housing in relation to one of the upper VARD chamber and the lower VARD chamber adapted to provide a signal for signaling the presence of air and/or for suctioning air through the VARD purge port.

3. (Original) The extracorporeal blood circuit of Claim 2, wherein the arterial filter having an upper arterial filter inlet chamber and a lower arterial blood chamber, whereby any air in the oxygenated blood accumulates in the upper arterial filter inlet chamber.

4. (Original) The extracorporeal blood circuit of Claim 3, wherein:

- the arterial filter further comprises an arterial filter purge port through the arterial filter housing to the upper arterial filter blood inlet chamber, and further comprising:
 - an arterial filter recirculation line extending between the arterial filter purge port and the venous return line coupled to the upper venous blood inlet, whereby air accumulating in the upper arterial filter inlet chamber is drawn by the blood pump into the upper VARD chamber.

5. (Original) The extracorporeal blood circuit of Claim 4, wherein the disposable circuit support module comprises:

a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD; and
the upper arterial filter fitting is configured to enable movement of the arterial filter from the upright position by the perfusionist to an inverted position to dislodge air bubbles into the arterial line.

6. (Original) The extracorporeal blood circuit of Claim 1, wherein:
the disposable circuit support module comprises a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD;

an oxygenator inlet line couples the oxygenator venous blood inlet to the blood pump outlet; and

a blood pump inlet line couples the blood pump inlet to the lower venous blood outlet of the VARD,

whereby the oxygenator inlet line and the blood pump inlet line support the blood pump, and the disposable circuit support module indirectly supports the blood pump.

7. (Original) The extracorporeal blood circuit of Claim 1, wherein the disposable circuit support module comprises:

a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD; and

the upper arterial filter fitting is configured to enable movement of the arterial filter from the upright position by the perfusionist to an inverted position to dislodge air bubbles into the arterial line.

8. (Original) The extracorporeal blood circuit of Claim 1, wherein the disposable circuit support module comprises a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD.

9. (Original) The extracorporeal blood circuit of Claim 8, wherein the disposable circuit support module comprises a receptacle adapted to be engaged to maintain the disposable circuit support module upright in 3-D space in relation to the patient.

10. (Original) The extracorporeal blood circuit of Claim 1, wherein the disposable circuit support module comprises a receptacle adapted to be engaged to maintain the disposable circuit support module upright in 3-D space in relation to the patient.

11. (Amended) The extracorporeal blood circuit of Claim 1, wherein:
the disposable circuit support module comprises a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD;

an oxygenator inlet line couples the oxygenator venous blood inlet to the blood pump outlet;

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a blood pump inlet line couples the blood pump inlet to the lower venous blood outlet of the VARD, whereby the oxygenator inlet line and the blood pump inlet line support the blood pump, and the disposable circuit support module indirectly supports the blood pump; and

a prime line coupled to the oxygenator inlet line adapted to be coupled to a prime solution source to enable retrograde filling of ~~[[the]]~~ at least a portion of the integrated extracorporeal blood circuit with prime solution.

12. (Amended) The ~~[[system]]~~ of Claim ~~[[30]]~~ 11, wherein the oxygenator inlet line and the blood pump inlet line are flexible, enabling movement of the blood pump with respect to the disposable circuit support module.

13. (Original) The extracorporeal blood circuit of Claim 11, further comprising a fluid infusion line coupled to the blood pump inlet line adapted to be coupled to a sequestering bag to store prime solution or venous blood.

14. (Original) The extracorporeal blood circuit of Claim 1, wherein the arterial line passes through a blood flow transducer connector that receives and supports a reusable blood flow transducer to make arterial flow rate measurements.

15. (Original) The extracorporeal blood circuit of Claim 1, wherein the venous support line comprises a connector for supporting a reusable instrument for measuring blood oxygen saturation and blood hematocrit of venous blood passing through the venous return line.

16. (Amended) The extracorporeal blood circuit of Claim 1, wherein the venous support line comprises a utility connector having ~~[[a plurality of]]~~ a plurality of luer ports and barbed ports.

17. (Original) The extracorporeal blood circuit of Claim 1, further comprising a manifold for sampling of venous and arterial blood and for drug administration.

18. (Original) A system of a disposable, extracorporeal blood circuit and reusable circuit holder for providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room and employing a venous return line and an arterial line coupled to the respective venous and arterial systems of the patient, the system comprising:

a blood pump having a blood pump inlet and a blood pump outlet and adapted to be operated to pump venous blood into the blood pump inlet and out of the blood pump outlet;

a venous air removal device (VARD) having an upper venous blood inlet coupled to the venous return line and a lower venous blood outlet coupled to the blood pump inlet;

a blood oxygenator having an oxygenator venous blood inlet coupled to the blood pump outlet and an oxygenated blood outlet, the blood oxygenator adapted to be operated to oxygenate venous blood;

an arterial filter having an arterial filter inlet coupled to the oxygenated blood outlet of the blood oxygenator and a arterial filter outlet coupled to the arterial line;

a disposable circuit support module supporting and spatially arranging the blood oxygenator, the VARD, the arterial filter, and the blood pump in 3-D space; and

a reusable circuit holder having a vertical mast adapted to extend vertically adjacent to the patient, and a support arm assembly extending laterally from the vertical mast engaging and supporting the disposable circuit support module above the floor of the operating room.

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19. (Original) The system of Claim 18, wherein the disposable circuit support module comprises a receptacle adapted to be engaged by a receiver of the support arm assembly to maintain the disposable circuit support module upright in 3-D space in relation to the patient and the floor of the operating room.

20. (Amended) [[The system of Claim 18,]] A system of a disposable, extracorporeal blood circuit and reusable circuit holder for providing extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery adapted to be performed in the presence of a perfusionist on a patient in an operating room and employing a venous return line and an arterial line coupled to the respective venous and arterial systems of the patient, the system comprising:

a blood pump having a blood pump inlet and a blood pump outlet and adapted to be operated to pump venous blood into the blood pump inlet and out of the blood pump outlet;

a venous air removal device (VARD) having an upper venous blood inlet coupled to the venous return line and a lower venous blood outlet coupled to the blood pump inlet;

a blood oxygenator having an oxygenator venous blood inlet coupled to the blood pump outlet and an oxygenated blood outlet, the blood oxygenator adapted to be operated to oxygenate venous blood;

an arterial filter having an arterial filter inlet coupled to the oxygenated blood outlet of the blood oxygenator and a arterial filter outlet coupled to the arterial line;

a disposable circuit support module supporting and spatially arranging the blood oxygenator, the VARD, the arterial filter, and the blood pump in 3-D space;

a reusable circuit holder having a vertical mast adapted to extend vertically adjacent to the patient, and a support arm assembly extending laterally from the vertical mast engaging and supporting the disposable circuit support module above the floor of the operating room; and

wherein the disposable circuit support module supports and spatially arranges the blood oxygenator, the VARD, the arterial filter, and the blood pump in 3-D space with the oxygenator venous blood inlet and the venous blood outlet of the blood pump supported at substantially the same elevation, the lower venous blood outlet of the VARD at a VARD outlet elevation above the venous blood inlet of the blood pump, the arterial line coupled to the arterial filter outlet of the arterial filter at an arterial line elevation higher than the VARD outlet elevation, the arterial filter inlet of the arterial filter at an arterial filter inlet elevation higher than the arterial line elevation, and the venous return line coupled to the upper venous blood inlet of the VARD at a venous return elevation, whereby the operation of the blood pump is assisted by gravity flow of venous blood through the venous return line and the VARD.

21. (Original) The system of Claim 18, wherein the VARD further comprises:
a VARD housing enclosing a lower VARD chamber coupled to the lower venous blood outlet and an upper VARD chamber coupled to the upper venous blood inlet;
a VARD purge port through the housing to the upper VARD chamber; and
an air sensor supported by the VARD housing in relation to one of the upper VARD chamber and the lower VARD chamber adapted to provide a signal for signaling the presence of air and/or for suctioning air through the VARD purge port.

22. (Original) The system of Claim 21, wherein the arterial filter having an upper arterial filter inlet chamber and a lower arterial blood chamber, whereby any air in the oxygenated blood accumulates in the upper arterial filter inlet chamber.

23. (Original) The system of Claim 22, wherein:
the arterial filter further comprises an arterial filter purge port through the arterial filter housing to the upper arterial filter blood inlet chamber, and further comprising:

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an arterial filter recirculation line extending between the arterial filter purge port and the venous return line coupled to the upper venous blood inlet, whereby air accumulating in the upper arterial filter inlet chamber is drawn by the blood pump into the upper VARD chamber.

24. (Original) The system of Claim 23, wherein the disposable circuit support module comprises:

a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD; and

the upper arterial filter fitting is configured to enable movement of the arterial filter from the upright position by the perfusionist to an inverted position to dislodge air bubbles into the arterial line.

25. (Canceled) Please cancel claim 25.

26. (Original) The system of Claim 18, wherein the disposable circuit support module comprises a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD.

27. (Original) The system of Claim 18, wherein the disposable circuit support module comprises a receptacle adapted to be engaged by the support arm assembly to maintain the disposable circuit support module upright in 3-D space in relation to the patient and to enable the rapid removal from and replacement of the extracorporeal blood circuit.

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28. (Original) The system of Claim 18, further comprising an electronics support assembly extending laterally from the vertical mast of the reusable circuit holder including an adjustable clamp for adjusting the vertical position of the electronics support assembly along the vertical mast.

29. (Amended) The system of Claim ~~[[1]]~~28, wherein:
the VARD further comprises:

a VARD housing enclosing a lower VARD chamber coupled to the lower venous blood outlet and an upper VARD chamber coupled to the upper venous blood inlet;

a VARD purge port through the housing to the upper VARD chamber; and
an air sensor supported by the VARD housing in relation to one of the upper VARD chamber and the lower VARD chamber adapted to provide a signal indicating the presence of air in the VARD housing;

a VARD purge line is coupled to the VARD purge port and extends to a purge line distal end connector adapted to be coupled to a vacuum source to apply suction to the VARD purge port;

the electronics support assembly supports an active air removal (AAR) controller having a air sensor signal input terminal and a pinch valve adapted to receive the VARD purge line, the air sensor signal input terminal adapted to be coupled to the air sensor by a VARD cable, the AAR controller opening the pinch valve when the air sensor signal indicates the presence of air in the VARD housing to purge air from the VARD housing;
and

the adjustable clamp enables adjusting the vertical position of the electronics support assembly along the vertical mast to dispose the pinch valve receiving the VARD purge line at substantially the same elevation as the VARD purge port.

30. (Original) The system of Claim 29, wherein the support arm assembly comprises a cable supporting and routing channel adapted to receive the VARD cable.

31. (Original) The system of Claim 18, wherein:
the disposable circuit support module comprises a lower oxygenator fitting engaging the oxygenator in an upright position; a lower VARD fitting engaging the VARD in an upright position, and an upper arterial filter fitting engaging the arterial filter in an upright position above the VARD; and wherein:

an oxygenator inlet line is coupled between the oxygenator venous blood inlet and the blood pump outlet; and

a blood pump inlet line is coupled between the blood pump inlet and the lower venous blood outlet of the VARD,

whereby the oxygenator inlet line and the blood pump inlet line support the blood pump, and the disposable circuit support module indirectly supports the blood pump.

32. (Original) The system of Claim 31, wherein the oxygenator inlet line and the blood pump inlet line are flexible, enabling tilting of the blood pump with respect to the disposable circuit support module.

33. (Original) The system of Claim 31, wherein:
the reusable circuit holder further comprises a hanger on the vertical mast above the disposable circuit module adapted to support at least one prime solution holding bag; and

the integrated extracorporeal blood circuit further comprises a priming line coupled to the oxygenator inlet line and extending to a line connector adapted to be connected to a prime solution holding bag supported by the hanger above the extracorporeal blood circuit.

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34. (Original) The system of Claim 33 wherein the disposable circuit support module supports the priming line to extend upward from the oxygenator inlet line

35. (Original) The system of Claim 33, wherein the reusable circuit holder further comprises a mast arm assembly that can be attached to a fixed point in the operating room and fixed at a selected position along the vertical mast to dispose the support arm assembly and disposable circuit support module extending laterally from the vertical mast, whereby the prime solution holding bag and the extracorporeal blood circuit can be raised or lowered together above the floor of the operating room in operative relation to the patient and the priming line length is minimized.

36. (Original) The system of Claim 31, wherein:
the reusable circuit holder further comprises a hanger on the vertical mast above the disposable circuit module adapted to support at least one recirculation bag having at least two bag lines; and

the integrated extracorporeal blood circuit further comprises:

a fluid infusion line coupled to the blood pump inlet line and extending to a line connector adapted to be connected to one bag line of a recirculation bag supported by the hanger above the extracorporeal blood circuit; and

a recirculation/cardioplegia line coupled to an oxygenator recirculation port and extending to a line connector adapted to be connected to a further bag line of the recirculation bag supported by the hanger above the extracorporeal blood circuit.

37. (Original) The system of Claim 36, wherein the disposable circuit support module supports the fluid infusion line and the recirculation/cardioplegia line to extend upward from the oxygenator recirculation port to a bag line of the recirculation bag.

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38. (Original) The system of Claim 37, wherein the reusable circuit holder further comprises a mast arm assembly that can be attached to a fixed point in the operating room and fixed at a selected position along the vertical mast to dispose the support arm assembly and disposable circuit support module extending laterally from the vertical mast, whereby the recirculation bag and the extracorporeal blood circuit can be raised or lowered together above the floor of the operating room in operative relation to the patient and the fluid infusion line length and the recirculation/cardioplegia line length are minimized.

39. (Original) The system of Claim 36, wherein the reusable circuit holder further comprises a mast arm assembly that can be attached to a fixed point in the operating room and fixed at a selected position along the vertical mast to dispose the support arm assembly and disposable circuit support module extending laterally from the vertical mast, whereby the recirculation bag and the extracorporeal blood circuit can be raised or lowered together above the floor of the operating room in operative relation to the patient and the fluid infusion line length and the recirculation/cardioplegia line length are minimized.

40. (Original) The system of Claim 18, wherein the arterial line passes through a blood flow transducer connector that receives and supports a reusable blood flow transducer to make arterial flow rate measurements.

41. (Original) The system of Claim 18, wherein the venous support line comprises a connector for supporting a reusable instrument for measuring blood oxygen saturation and blood hematocrit of venous blood passing through the venous return line.

AMENDMENT AND RESPONSE

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42. (Amended) The system of Claim 18, wherein the venous support line comprises a utility connector having [[a plurality of]]a plurality of luer ports and barbed ports.

43. (Original) The system of Claim 18, further comprising a manifold for sampling of venous and arterial blood and for drug administration.